PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P16552PC00	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/SE 03/01195	International filing date *(day/month/year)* 08.07.2003	Priority date *(day/month/year)* 09.07.2002
International Patent Classification (IPC) or both national classification and IPC A61M39/10		
Applicant CARMEL PHARMA AB et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
09.02.2004	29.10.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Hedels, B Telephone No. +49 89 2399-2329

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/SE 03/01195

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-7 as originally filed

Claims, Numbers

1-10 filed with telefax on 11.10.2004

Drawings, Sheets

1/4-4/4 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 4-7

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 4-7 are so unclear that no meaningful opinion could be formed *(specify)*:

   see separate sheet

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-3,8-10
	No:	Claims	
Inventive step (IS)	Yes:	Claims	3
	No:	Claims	2,8-10
Industrial applicability (IA)	Yes:	Claims	1-10
	No:	Claims	

2. Citations and explanations

see separate sheet

Concerning section III.

Claims 4-7 do not meet the requirement of clarity (Art. 6 PCT). They relate to an injection component 11 which is not part of the invention according to claim 1. Thus they define the relationship to another device rather than specify the injection device of claim 1 per se (see the Guidelines for Examination, C-III, 4.8a).

Concerning section V.

1. The injection device disclosed in US-A-5 158 554 (D2) (see Fig. 15) corresponds to the device depicted in Figs. 2 and 2a of the application and it comprises all the features of claim 1 with the exception of the first Luer fitting provided with a thread. As the lower end of the tubing 172 in Fig. 15 of D2 is not illustrated, it is clear that the above feature is not disclosed in D2.

Such Luer fittings were, however, not only common practice in this technical field but one of them is even illustrated in D2, Fig. 3.
It goes without saying that the skilled person would have provided such a generally known Luer fitting at the lower end of the device depicted in Fig. 15 if the lower end of the tubing 172 should be connected to a cannula inserted into a patient.

The arrangement of such a Luer fitting at the lower end of the tubing 172 is therefore on no rate regarded as involving an inventive step (Art. 33(3) PCT).

2. The features of the dependent claims 2 and 8-10 are also disclosed in D2 (see Fig. 15 and the corresponding description). Hence, these features also lack an inventive step.

3. The provision of a fourth path as defined in claim 3 is novel and cannot be derived in an obvious manner from the cited documents. Hence, this feature meets the requirements of Art. 33(2) and (3) PCT.

4. Claim 1 has not been properly delimited with respect to D2 as in Fig. 15 of D2, the first, second and third connecting components and the body are designed as an integrated unit in the same manner as depicted in Figs. 2 and 2a of the application (Rule 6.3 (b)).

5. The description should have been brought into line with the new claims (Rule 5.1

(a) (iii)).

6. D2 should in addition have been indicated in the description (Rule 5.1 (a) (ii)).

CLAIMS

1. A device for injection, comprising a body (1) provided with a first channel (2) for conveyance of a first medical substance and a first connecting component (3) having a first port (4) for introduction of a first medical substance into said first channel (2), said connecting component (3) being connectable to an external unit, and a second channel (5) for conveyance of a second medical substance and a second connecting component (6) having a second port (7) which can be opened by means of an injection component for injecting a second medical substance into said second channel (5), and provided with a third connecting component (8) being common to the first and the second channels (2, 5) and having at least one third port (9) for conveying medical substances out from said first and second channels, **characterized in** that said first (3), second (6) and third (8) connecting components and the body (1) are designed as an integrated unit, and said third connecting component (8) is a first luer fitting component provided with a thread (19) for releasable connection with a second luer fitting component having a corresponding thread, for creating a luer fitting coupling.

2. A device according to claim 1, **characterized in** that the body (1) has a channel portion (12) common to the first (2) and the second (5) channels, and said third port (9) constitutes an outlet for this channel portion (12) and thereby an outlet common to the first and the second channels.

3. A device according to claim 1, **characterized in** that said third connecting component (8a) has a fourth port (23), wherein said third port (9a) constitutes an outlet for the first channel (2a) and said fourth port (23) constitutes an outlet for the second channel (5a).

4. A device according to any preceding claim, **characterized in** that said second port (7) has a first flexible membrane (17) for cooperation with a second flexible membrane arranged in an injection component (11) which is connectable to said second connecting component (6).

5. A device according to claim 4, **characterized in** that the device has a means (18) for holding said second flexible membrane with a pressure against said first membrane (17).

6. A device according to claim 5, **characterized in** that the pressure exceeds the yield point of the first and the second membranes.

7. A device according to claim 5 or 6, **characterized in** that the pressure exceeds 150 kPa.

8. A device according to any preceding claim, **characterized in** that the first luer fitting component comprises a male fitting (20) intended to cooperate with a corresponding female fitting of said second luer fitting component, which female fitting has a further channel, to form a connection sealed relative to the environment between the first (2) and the second (5) channels on one hand and said further channel on the other hand.

9. A device according to claim 8, **characterized in** that the first luer fitting component comprises a ring (21) which is concentrically arranged relative to the male fitting (20) and at least partly encloses the male fitting (20), the ring being provided with said thread (19).

10. An injection arrangement comprising a device according to any of claims 1-9 for transmitting a first medical substance from an infusion bag (10) connected to said first connecting component (3) of the device, via the first channel (2), to a receiving unit connected to said third connecting component (8) of the device, and for transmitting a second medical substance from an injection component (11) connected to said second connecting component (6) of the device, via the second channel (5), to said receiving unit.